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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,468	02/07/2000	Ralph Alderson	PF112U1	1320

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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/499,468	ALDERSON ET AL.	
	Examin r	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 IDS's* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. The Amendment, filed 7/10/03, has been entered into the record.

B. Claims 12, 19, 28, 34, 36-38 and 42-71 were pending in the application. In the amendment filed 7/10/03, Applicants canceled claims 12, 19, 28, 34 and 36-38. Therefore, claims 42-71 are pending and are the subject of this Office Action.

C. The Information Disclosure Statement, filed 7/10/03, has been entered into the record.

D. The Information Disclosure Statement, filed 6/20/03, has been entered into the record.

E. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Information Disclosure Statement

A. Applicants have requested that the Information Disclosure Statements filed 3/12/01, 1/23/02, 4/18/02, 8/16/02 and 9/12/02 be considered and initialed. However, these Information Disclosure Statements could not be located in the file.

B. The Examiner has considered the references on the Information Disclosure Statements filed 6/20/03 and 7/10/03. However, references GW-HB have been lined through since these applications are not commonly owned. The Examiner noticed that references GW, GX and GY have issued as U.S. Patents and included these on a Form PTO-892. However, references GZ, HA and HB have not issued as patents and, therefore, have not been considered by the Examiner.

3. Drawings

A. Figures 1A-1E are objected to by the Examiner since these Figures recite "match with Figure __." This phrase should be removed from the bottom of each of these drawings, to be consistent with Figure 2.

4. Title

A. The objection to the title has been withdrawn in view of Applicants' amendment.

5. Double Patenting

A. All rejections under the judicially created doctrine of obviousness-type double patenting regarding U.S. Patent 5,932,540; 09/107,997; 10/084,488; 10/127,551; 10/120,398 and, 10/060,523 are maintained. Applicants argue that they have amended the claims to recite a "method of treating a patient having an injury to or degeneration of a photoreceptor cell" and that the method uses "a therapeutically effective amount" of the VEGF-2 protein and that neither of these claim amendments are disclosed or suggested by the claims recited in the applications or patent. This argument has been considered, but is not deemed persuasive. It would be expected that any individual, especially after birth, would experience degeneration of a photoreceptor cell (e.g. needing reading glasses). Therefore, the patents and applications cited in the double patenting rejection would still read on the present invention, since administering VEGF to any patient for any reasons would still be expected to treat a degenerating photoreceptor, including people, for example, with less than 20/20 vision. It is also brought to Applicants' attention that people with "perfect" vision would still be expected to have at least one photoreceptor which is degenerating.

6. Claim Rejections - 35 USC § 112, first paragraph – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 42-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 42 recites a method of treating a patient having an injury to or a degeneration of a photoreceptor cell by administering a VEGF-2 fragment. **This is a new matter rejection**. Applicants are only enabled for methods of treating patient by proliferating photoreceptor cells. The amendment to claim 42 broadens the scope of the claim to recite treating a patient by affecting photoreceptor cells in any capacity, other than by proliferating photoreceptors (e.g. hypertrophy).

7. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 42-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of proliferating photoreceptors in a patient by administering a VEGF-2 fragment, does not reasonably provide enablement for a method of treating a patient having any injury to, or degeneration of, a photoreceptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to *** the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to Applicants claiming a method of treating any and all injuries to photoreceptors, or for treating a degenerating photoreceptor. Applicants have only demonstrated that they are able to proliferate photoreceptor cells in vitro (Example 8). Applicants have provided no guidance and working examples of using VEGF to treat a patient in vivo, nor have Applicants taught that they are able to treat any and all injuries to photoreceptors by administering VEGF-2. Photoreceptor injuries could lead to, for example, hyperplasia or a temporary altered functioning of a photoreceptor where proliferation of the cell would not be required, such as a toxin which inactivates (possibly temporarily) photoreceptors. Applicants have provided no guidance or working examples of how to use VEGF-2 to treat these situations. Furthermore, Applicants have not demonstrated that photoreceptor proliferation is always achievable. It is well-known in the art that contact inhibition prevents cells from excessive proliferation. This occurs when cells make contact with each other. Therefore, it is not clear that by simply administering VEGF to a patient who has not actually lost photoreceptors, that new receptors will grow, since many injuries may not lead to an area in the eye which is void of cells in order to permit other cells to proliferate. Furthermore, since it is not clear that the animal model in Example 8 is an art-accepted model of in vivo treatment of photoreceptors, it is not predictable to the artisan how to not only use VEGF to proliferate photoreceptor cells in a patient, but it is also not predictable how to treat any and all photoreceptor injury using VEGF-2.

In summary, the breadth of the claims is excessive with regard to Applicants claiming any in vivo method of treating a photoreceptor injury which does not include proliferation of photoreceptors. However, Applicants have not provided any guidance or working examples of any in vivo treatment of photoreceptors, nor is it predictable how to use VEGF to treat any photoreceptor injury in a patient, including proliferation. For these reasons, the Examiner has concluded that undue experimentation would be required to practice the claimed invention.

8. Claim Rejections - 35 USC § 102

A. Claims 42-71 remain rejected under 35 USC 102 as being anticipated by either U.S. Patent 5,932,540 or U.S. Patent 6,130,071. Applicants argue that they have amended the claims to recite a "method of treating a patient having an injury to or degeneration of a photoreceptor cell" and that the method uses "a therapeutically effective amount" of the VEGF-2 protein and that neither of these claim amendments are disclosed or suggested by the claims recited in the patents. This argument has been considered, but is not deemed persuasive for the reasons provided in the above double patenting rejection.

9. Claim Rejections - 35 USC § 102/103

A. Claims 50, 51, 60, 61, 70 and 71 remain rejected under either 35 USC 102(e) or 35 U.S.C. 103(a) as being unpatentable over Alitalo et al. (U.S. Patent 6,130,071). Applicants argue that they have amended the claims to recite a "method of treating a patient having an injury to or degeneration of a photoreceptor cell" and that the method uses "a therapeutically effective amount" of the VEGF-2 protein and that neither of these claim amendments are disclosed or suggested by the claims recited in the patents. This argument has been considered, but is not deemed persuasive for the reasons provided in the above double patenting rejection.

10. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 15, 2003